

14230 U.S. PTO  
020304

PTO/SB/05 (08-03)

# UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	021989000411
First Inventor	BURT, David S.
Title	PROTEOSOME INFLUENZA VACCINE
Express Mail Label No.	EL 980213995 US

<b>APPLICATION ELEMENTS</b> See MPEP chapter 600 concerning design patent application contents.	<b>ADDRESS TO</b> Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450		
1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original and a duplicate for fee processing)	7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)		
2. <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.	8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)		
3. <input checked="" type="checkbox"/> Specification [Total Pages 39 ] (preferred arrangement set forth below) - Descriptive title of the Invention - Cross Reference to Related Applications - Statement Regarding Fed sponsored R & D - Reference to sequence listing, a table, or a computer program listing appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (if filed) - Detailed Description - Claim(s) - Abstract of the Disclosure	a. <input type="checkbox"/> Computer Readable Form (CRF) b. Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> paper number of pages c. <input type="checkbox"/> Statements verifying identity of above copies		
4. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets 7 ]	<b>ACCOMPANYING APPLICATIONS PARTS</b>		
5. Oath or Declaration [Total Pages 4 ] a. <input type="checkbox"/> Newly executed (original or copy) b. <input checked="" type="checkbox"/> Copy from a prior application (37 CFR 1.63 (d)) (for a continuation/divisional with Box 18 completed) i. <input type="checkbox"/> <b>DELETION OF INVENTOR(S)</b> Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).	9. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) 10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input checked="" type="checkbox"/> Power of (when there is an assignee) Attorney 11. <input type="checkbox"/> English Translation Document (if applicable) 12. <input type="checkbox"/> Information Disclosure <input type="checkbox"/> Copies of IDS Statement (IDS)/PTO-1449 Citations 13. <input type="checkbox"/> Preliminary Amendment 14. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) (Should be specifically itemized) 15. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed) 16. <input type="checkbox"/> Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent 17. <input checked="" type="checkbox"/> Other: Submission of Divisional Application		
18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76: <input type="checkbox"/> Continuation <input checked="" type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-part (CIP) of prior application No: 09/788,280 Prior application information: Examiner U. Winkler Art Unit: 1648			
For CONTINUATION OF DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.			
<b>19. CORRESPONDENCE ADDRESS</b>			
<input checked="" type="checkbox"/> Customer Number 20350 OR <input type="checkbox"/> Correspondence address below			
Name			
Address			
City	State Zip Code		
Country	Telephone Fax		
Name (Print/Type)	Karen B. Dow	Registration No. (Attorney/Agent)	29,684
Signature	Karen Babyak Dow	Date	February 3, 2004

60095047 v1

# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 514

## Complete if Known

Application Number	
Filing Date	Herewith
First Named Inventor	Burt, David S.
Examiner Name	Unassigned
Art Unit	Unassigned
Attorney Docket No.	021989-000411

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:
Deposit  
Account  
Number

20-1430

Deposit  
Account  
Name

Townsend and Townsend and Crew LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

## 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	385
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1)

(\$ ) 385

## 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below		Fee Paid
12	-20** =	0	X\$9			\$0
Independent Claims	6	-3** =	3	X\$43		\$129
Multiple Dependent						

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2)

(\$ ) 129

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

## 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Petitions related to provisional applications	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid SUBTOTAL (3)

(\$ )

## SUBMITTED BY

Complete (if applicable)

Name (Print/Type)	Karen B. Dow	Registration No. (Attorney/Agent)	29,684	Telephone	858-350-6100
Signature	Karen Babuak Dow			Date	February 3, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

DAVID S. BURT, et al.

Application No.: Unassigned

Filed: Herewith

For: PROTEOSOME INFLUENZA  
VACCINE

Examiner: Unassigned

Art Unit: Unassigned

**SUBMISSION OF DIVISIONAL  
APPLICATION**

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Mail Stop Patent Application  
Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This divisional application claims priority from U.S. non-provisional application serial no. 09/788,280, filed 15 February 2001, the contents of which are incorporated herein by reference, which claims priority from U.S. provisional application no.60/182,476, filed 15 February 2000, the contents of which are incorporated herein by reference.

In the response to the Office Action dated October 8, 2002 issued in the parent application, restriction to one of the following inventions was required under 35 U.S.C. 121:

I. Claims 1-8, 14-22, 35-49, and 56 drawn to a method of preparing a vaccine by combining an antigen in with a proteosome in the presence of a detergent followed by removing the detergent, classified in class 424, subclass 206.1.

II. Claims 23-27, and 57 drawn to a method of eliciting an immune response against an infectious agent such as influenza, classified in class 424, subclass 9.2.

III. Claims 28-30, drawn to an improved method of preparing proteosomes, classified in class 530, subclass 412.

IV. Claims 9-13 and 31-34, drawn to a composition a vaccine against an infectious agent, such as influenza, classified in class 424, subclass 209.1.

V. Claims 50, 51, 54, and 55, drawn to a composition a vaccine against an allergen, classified in class 424, subclass 275.1.

VI. Claims 50 and 52, drawn to a composition a vaccine against a cancer antigen, classified in class 424, subclass 277.1.

VII. Claims 50 and 53, drawn to a composition a vaccine against a biologic threat agent, classified in class 424, subclass 236.1.

VIII. Claim 57, drawn to a method of preventing or treating allergies, classified in class 424, subclass 9.2.

IX. Claim 57, drawn to a method of preventing or treating cancer, classified in class 424, subclass 9.2.

X. Claim 57, drawn to a method of preventing or treating exposure to a biologic threat agent, classified in class 424, subclass 9.2.

In the response to the Restriction Requirement issued in the parent application 09/788,280, received by the USPTO on November 8, 2002, Applicant elected Group IV (claims 9-13 and 31-34), with traverse. Because the elected Group IV is drawn to compositions or products, MPEP §821.04 states, "if applicant elects claims directed to the product and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. Applicants, therefore, requested rejoinder of claims within Group I.

In the Notice of Allowance issued in parent application 09/788,280 on December 19, 2003, the Examiner allowed claims 9-11, 31, 33, 58 and 61-63 directed to an allowable product (Group IV) and claims 1, 5, 6, 14, 18, 30, 59 and 60 directed to the process of making or using the patentable product (Group I), previously withdrawn from consideration as a result of the Restriction Requirement. Process claims 1, 5, 6, 14, 18, 30, 59 and 60 were rejoined and

fully examined for patentability under 37 CFR 1.104. Therefore, the restriction requirement among Group I and Group IV of paper No. 16 in the parent application was withdrawn.

In the instant Divisional Application filed herewith, Applicants respectfully request examination of the Group II claims from the parent application corresponding to claims 23-27, and claim 57 drawn to a method of eliciting an immune response against an infectious agent such as influenza, classified in class 424, subclass 9.2. In the instant application claims 23-27 have been renumbered 1-5 respectively, and previous multiple dependent claim 57 has been redrafted as five separate independent claims numbered 8-12. New claims 8-12 incorporate the limitations of previously presented claim 57 of the parent application. New dependent claim 6 has been added and support for multivalent vaccine recited therein is found in the specification on page 10, lines 14-16; page 12, lines 23-27; and page 16 lines 20-25. New dependent claim 7 has been added and support for said vaccine comprising one influenza antigen recited therein is found in the specification on page 7, lines 1-4; and page 12, lines 22-27.

Finally, in the parent application 09/788,280 Applicant received a Notice to File Missing Parts mailed March 20, 2001, which indicated that Figures 5E-F were referenced in the original parent specification as filed, but not supplied with the initial application. Applicant has therefore deleted all references to Figures 5E-F in the instant application and has attached hereto a formal drawing for Figures 5A-D. Furthermore, the drawings as filed in the parent application and included herein include a Figure 2A and 2B, wherein the Brief Description of the Drawings of the parent application only describes the drawings as Figure 2. Therefore, the specification in the instant application has been corrected to read "Figures 2A and 2B show mucosal immune responses induced by these vaccines."

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 20-1430. Applicants are requesting small entity status for this application.

Respectfully submitted,



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Reg. No. 29,684

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